

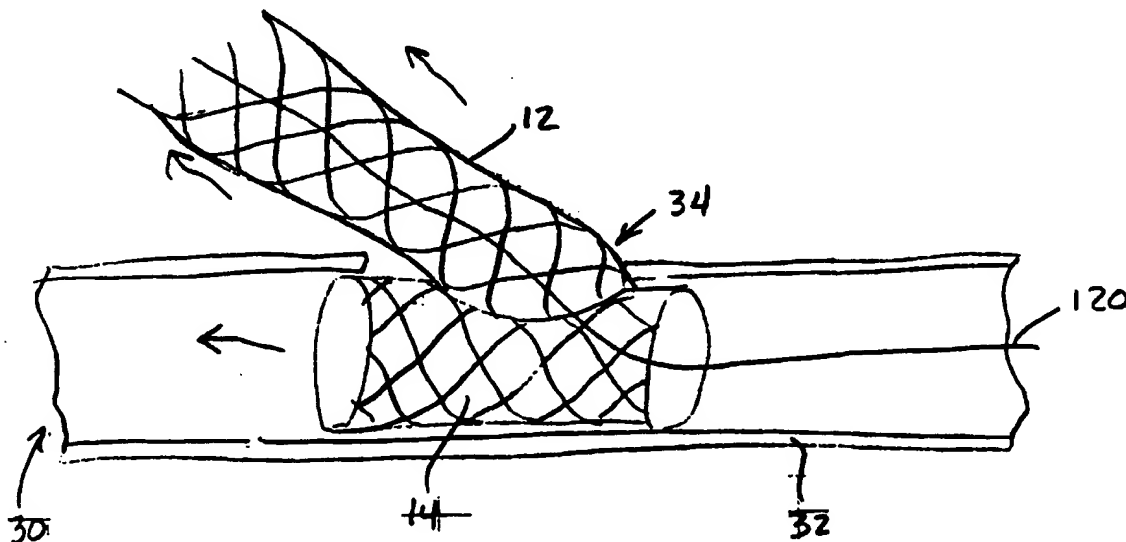
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## INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

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			(43) International Publication Date: 14 May 1998 (14.05.98)
(21) International Application Number: PCT/US97/19947			(81) Designated States: AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GE, GH, HU, ID, IL, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, UZ, VN, YU, ZW, ARIPO patent (GH, KE, LS, MW, SD, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG).
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(71) Applicant: VASCULAR SCIENCE INC. [US/US]; Suite 202, 701 Decatur Avenue North, Minneapolis, MN 55427 (US).			
(72) Inventors: BERG, Todd, Allen; 1571 Broken Oak Court, Lino Lakes, MN 55038 (US). BACHINSKI, Thomas, J.; 19059 Orchard Trail, Lakeville, MN 55044 (US). PETERSON, Alex, Alden; 17650 82nd Way North, Maple Grove, MN 55311 (US). BOLDENOW, Gregory, Alan; 6809 Valley Place North, Crystal, MN 55427 (US).			
(74) Agents: JACKSON, Robert, R. et al.; Fish & Neave, 1251 Avenue of the Americas, New York, NY 10020 (US).			

(54) Title: TUBULAR MEDICAL GRAFT CONNECTORS



## (57) Abstract

Connectors are provided for making connections between tubular conduits in medical procedures such as those involving treatment of a patient's circulatory system. The connectors are variously configured for making end-to-side or end-to-end connections of tubular conduits. One of the tubular conduits may be a graft conduit, which can be artificial conduit, natural conduit, or a combination of both. The connectors for making end-to-side connections can be generally T-shaped or L-shaped. Various portions of the connectors can attach to the inside or outside of the associated conduit, depending on the connector configuration that is selected.

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<b>(51) International Patent Classification <sup>6</sup> :</b> <b>A61F 2/06, A61B 17/11</b>		<b>A3</b>	<b>(11) International Publication Number:</b> <b>WO 98/19630</b>
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<b>(21) International Application Number:</b> PCT/US97/19947 <b>(22) International Filing Date:</b> 5 November 1997 (05.11.97)  <b>(30) Priority Data:</b> 08/745,618 7 November 1996 (07.11.96) US 08/839,199 23 April 1997 (23.04.97) US 08/958,937 28 October 1997 (28.10.97) US  <b>(71) Applicant:</b> VASCULAR SCIENCE INC. [US/US]; Suite 202, 701 Decatur Avenue North, Minneapolis, MN 55427 (US).  <b>(72) Inventors:</b> BERG, Todd, Allen; 1571 Broken Oak Court, Lino Lakes, MN 55038 (US). BACHINSKI, Thomas, J.; 19059 Orchard Trail, Lakeville, MN 55044 (US). PETERSON, Alex, Alden; 17650 82nd Way North, Maple Grove, MN 55311 (US). BOLDENOW, Gregory, Alan; 6809 Valley Place North, Crystal, MN 55427 (US).  <b>(74) Agents:</b> JACKSON, Robert, R. et al.; Fish & Neave, 1251 Avenue of the Americas, New York, NY 10020 (US).			<b>(81) Designated States:</b> AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GE, GH, HU, ID, IL, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, UZ, VN, YU, ZW, ARIPO patent (GH, KE, LS, MW, SD, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG).  <b>Published</b> <i>With international search report.</i> <i>Before the expiration of the time limit for amending the claims</i> <i>and to be republished in the event of the receipt of amendments.</i>  <b>(88) Date of publication of the international search report:</b> 8 October 1998 (08.10.98)
<b>(54) Title:</b> TUBULAR MEDICAL GRAFT CONNECTORS			
<p>The diagram illustrates a tubular medical graft connector. It features a main horizontal tube (120) on the right. A mesh-like structure (12) is shown in cross-section, with arrows indicating flow direction. The mesh is connected to a larger tube (120) on the right. Arrows indicate flow direction. Labels 30, 32, 34, and 14 are also present.</p>			
<b>(57) Abstract</b> <p>Connectors are provided for making connections between tubular conduits in medical procedures such as those involving treatment of a patient's circulatory system. The connectors are variously configured for making end-to-side or end-to-end connections of tubular conduits. One of the tubular conduits may be a graft conduit, which can be artificial conduit, natural conduit, or a combination of both. The connectors for making end-to-side connections can be generally T-shaped or L-shaped. Various portions of the connectors can attach to the inside or outside of the associated conduit, depending on the connector configuration that is selected.</p>			

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# INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 97/19947

A. CLASSIFICATION OF SUBJECT MATTER  
IPC 6 A61F2/06 A61B17/11

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 6 A61F A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 95 14442 A (UNIV JOHNS HOPKINS) 1 June 1995	1-3, 8-14,16, 18,23-25
A	see the whole document	15,17, 21,22
X	US 4 728 328 A (HUGHES HOWARD C ET AL) 1 March 1988	1-4, 8-11,20
A	see column 7, line 3 - line 23; figures see column 5, line 51 - line 62	5,32,37, 44
X	EP 0 684 022 A (ENDOVASCULAR TECH INC) 29 November 1995	1,2,4, 16-18
A	see figures	23
	- / - -	

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

\* Special categories of cited documents :

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31 July 1998

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## INTERNATIONAL SEARCH REPORT

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## C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 0 686 379 A (CARDIOVASCULAR CONCEPTS INC) 13 December 1995 see the whole document	1-4,16, 18,21,22
A	---	23
X	GB 489 316 A (DAVIS & GECK, INC.) 25 July 1938 see page 1, line 33 - line 96; figures	1-3
A	---	21
X	US 4 470 415 A (WOZNIAK JOHN J) 11 September 1984 see column 5, line 17 - line 27; figures	32,35
A	---	
	US 5 234 448 A (WHOLEY MARK H ET AL) 10 August 1993 see column 3, line 1 - line 19; figures 1,2,4 -----	32-34, 37,44,45

# INTERNATIONAL SEARCH REPORT

International application No.  
PCT/US 97/19947

## Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 26-31  
because they relate to subject matter not required to be searched by this Authority, namely:  
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery
2. ☐ Claims Nos.:  
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. ☐ Claims Nos.:  
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

## Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. ☒ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

### Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☒ No protest accompanied the payment of additional search fees.

**FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210**

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. Claims: 1-22,23-25

Connector comprising two tubular sections which are transverse to each other and connected to tubular structures in a patient

2. Claims: 32-49

A connecting structure between two conduits in a patient comprising an annular component with a larger circumference than the conduit in order to compress the conduit coaxially.



# INTERNATIONAL SEARCH REPORT

Inter national Application No

PCT/US 97/19947

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
W0 9514442 A	01-06-1995	US 5443497 A AU 1256095 A EP 0730436 A JP 9511409 T	22-08-1995 13-06-1995 11-09-1996 18-11-1997
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## TUBULAR MEDICAL GRAFT CONNECTORS

### Background of the Invention

This invention relates to tubular medical grafts, and more particularly to connectors for use in making tubular connections between tubular grafts and a patient's tubular tissue structures.

Goldsteen et al. U.S. patent application No. 08/745,618, filed November 7, 1996, Sullivan et al. U.S. patent application 08/844,992, filed April 23, 1997, and Sullivan et al. U.S. patent application 08/869,808, filed June 5, 1997 (all of which are hereby incorporated by reference herein) show examples of medical procedures in which it is necessary to make one or more tubular connections between a patient's tubular body tissue structures and a tubular graft. The graft may be either natural body tissue relocated from elsewhere in the patient's body, an artificial graft structure, or a combination of natural and artificial structures. In the exemplary procedures shown in the three references mentioned above it is typically necessary to connect an end of the graft to a side wall of the patient's pre-existing body tubing, but it may

- 2 -

also sometimes be necessary to connect an end of a graft to an end of a pre-existing body tube. The three references mentioned above deal primarily with procedures that are performed to the greatest extent possible percutaneously and through lumens of a patient's tubular body structures. Thus graft connectors are sometimes needed that can be delivered and installed via such lumens. At other times, however, graft connectors are needed that can be installed during more traditional surgical procedures.

It is important for graft connectors to be easy and quick to install (whether percutaneously or surgically), but to be secure after installation. It is typically preferred for a graft connector to be relatively flexible after installation so that it does not form an unnaturally rigid structure in the patient's body. Improvements are constantly sought in all of these aspects of graft connectors.

In view of the foregoing, it is an object of this invention to provide improved tubular graft connectors for making tubular connections between tubular grafts and a patient's tubular body tissue structures.

It is a more particular object of this invention to provide tubular graft connectors that are easy and quick to install, in some cases percutaneously and in some cases surgically, but which are strong and secure after installation.

#### Summary of the Invention

These and other objects of the invention are accomplished in accordance with the principles of the invention by providing tubular graft connector structures that, for making end-to-side connections

- 3 -

between an end of a graft and a side wall of a patient's tubular body structure, have a first tubular section for tubular attachment to the graft and a second tubular section transverse to the first section for tubular attachment to the patient's tubular body structure. The second section may extend transversely in only one direction from the first section, making a somewhat L-shaped connector. Or the second section may extend transversely in both directions from the first section, making a T-shaped connector. The second section may be adapted to fit concentrically within the patient's tubular body structure, with the first section extending from an aperture in the side wall of that body structure. The first section may be connected in advance to the end of the graft. For example, if the graft is or includes an artificial tubular structure, the first section may be integral with or otherwise attached to that artificial structure. Alternatively, if the graft is or includes a natural tubular structure, the first section may be tubularly connected either inside or outside of that structure.

Connector structures of this invention may include a substantially annular component which fits around an axial end portion of a graft conduit and which is circumferentially compressible to annularly engage that conduit. The annular component may have radially inwardly extending prongs for enhancing the engagement of the graft conduit. Resilient fingers may be resiliently biased to extend radially outward adjacent an axial end portion of the annular structure to retain the annular structure in an aperture in a side wall of a patient's pre-existing body conduit. Alternatively, for use in making an end-to-end

- 4 -

connection, the connector structure may include a second substantially annular component similar to the first component for attachment to an end portion of a second body conduit similar to the attachment of the first component to the graft conduit.

The invention also includes certain methods and apparatus which can be used in the installation of graft connectors.

Further features of the invention, its nature and various advantages, will be more apparent from the accompanying drawings and the following detailed description of the preferred embodiments.

#### Brief Description of the Drawings

FIG. 1 is a simplified elevational view of an illustrative embodiment of a tubular graft connector and part of illustrative apparatus for installing a tubular graft connector, all in accordance with this invention.

FIG. 2 is a view similar to FIG. 1 showing a later stage in use of the FIG. 1 connector and apparatus in accordance with the invention.

FIG. 3 is another view similar to FIG. 2 showing a still later stage in use of the FIG. 1 connector and apparatus in accordance with the invention.

FIG. 4 is a simplified view, partly in section, of another stage in use of the FIG. 1 connector and apparatus in accordance with the invention.

FIG. 5 is a view similar to FIG. 4 showing a later stage in use of the connector and apparatus in accordance with the invention.

- 5 -

FIG. 6 is another view similar to FIG. 5 showing a still later stage in use of the connector and apparatus in accordance with the invention.

FIG. 7 is still another view similar to  
5 FIG. 6 showing yet a later stage in use of the connector and apparatus in accordance with the invention.

FIG. 8 is yet another view similar to FIG. 7 showing a still later stage in use of the connector and  
10 apparatus in accordance with the invention.

FIG. 9 is a simplified elevational view showing in more detail a possible construction of a connector of the type shown in FIG. 1.

FIG. 10 is a simplified elevational view of a  
15 portion of the FIG. 9 apparatus at a predetermined point in its fabrication.

FIG. 11 is a view similar to FIG. 10 showing a later stage in the fabrication process.

FIG. 12 is a simplified elevational view  
20 showing in more detail another possible construction of a connector of the type shown in FIG. 1.

FIG. 13 is a simplified elevational view, partly in section, showing an illustrative use of a connector of this invention in a patient.

25 FIG. 14 is another view similar to FIG. 13 showing an illustrative use of an alternative connector in accordance with this invention.

FIG. 14a is yet another view similar to  
FIGS. 13 and 14 showing another illustrative embodiment  
30 of the invention.

FIG. 15 is a simplified elevational view, partly in section, of another illustrative embodiment of a graft connector in accordance with this invention.

- 6 -

FIG. 16 is another view similar to FIG. 15 showing a later stage in use of the connector of FIG. 15.

FIG. 17 is a view taken generally along the line 17-17 in FIG. 16, but with additional structure in accordance with this invention added.

FIG. 18 is a simplified elevational view of yet another illustrative embodiment of a graft connector in accordance with this invention.

FIG. 19 is another view similar to FIG. 18 showing another operating condition of the connector of FIG. 18.

FIG. 20 is another simplified elevational view, partly in section, showing a connector like the FIG. 18 connector in use.

FIG. 21 is another view similar to FIG. 20 with additional structure in accordance with the invention added.

FIG. 22 is a simplified perspective view of a structure like that shown in FIG. 21.

FIG. 23 is a simplified elevational view of still another illustrative graft connector in accordance with the invention.

FIG. 24 is another view similar to FIG. 23 showing another operating condition of the FIG. 23 connector.

FIG. 25 is a simplified elevational view, partly in section, taken perpendicular to the view shown in FIG. 24.

FIG. 26 is a simplified perspective view of an illustrative embodiment of a portion of a connector in accordance with the invention.

FIG. 27 is a view similar to FIG. 26 showing another operating condition of the FIG. 26 apparatus.



- 7 -

FIG. 28 is a simplified sectional view of an illustrative embodiment of a portion of a connector in accordance with the invention and instrumentation usable in applying the connector.

5           FIG. 29 is a simplified perspective view of another illustrative embodiment of a portion of a connector in accordance with the invention.

FIG. 30 is a simplified elevational view of an illustrative embodiment of a somewhat different type  
10 of connector in accordance with the invention.

FIG. 31 is a simplified end view of the connector shown in FIG. 30.

FIG. 32 is a view similar to FIG. 30 showing a later stage in use of the FIG. 30 connector.

15           FIG. 33 is another view similar to FIG. 30 showing another illustrative embodiment of a connector of the general type shown in FIG. 30.

FIG. 34 is another view similar to FIG. 33 showing a later stage in use of the FIG. 33 connector.

20           FIG. 35 is another view similar to FIG. 34 showing a still later stage in use of the FIG. 33 connector.

FIG. 36 is a simplified elevational view of an illustrative embodiment of still another somewhat  
25 different type of connector in accordance with the invention.

FIG. 37 is another view similar to FIG. 36 showing a later stage in use of the connector shown in FIG. 36.

30           FIG. 38 is another view similar to FIG. 37 showing a still later stage in use of the connector shown in FIG. 36.

FIG. 39 is a simplified end view of the connector shown in FIG. 36.

- 8 -

FIG. 40 is a simplified elevational view of another illustrative embodiment of a connector in accordance with the invention.

FIG. 41 is a simplified end view of the  
5 connector shown in FIG. 40.

FIG. 42 is a simplified perspective view of still another illustrative embodiment of a connector in accordance with this invention.

FIG. 43 is an elevational view of a connector  
10 of the type shown in FIG. 42 in use.

#### Detailed Description of the Preferred Embodiments

An illustrative embodiment of a tubular graft connector 10 in accordance with this invention for connecting the end of a tubular graft to an aperture in  
15 the side wall of a patient's tubular body tissue structure is shown in FIG. 1. Connector 10 includes a tubular first section 12 tubularly connected to a tubular second section 14. The longitudinal axis of second section 14 extends transversely to the  
20 longitudinal axis of first section 12. It will be understood that "transverse" can mean perpendicular, but it can also mean acute or obtuse angles other than 90°. In the particular embodiment shown in FIG. 1, second section 14 extends in both directions from the  
25 adjacent end of first section 12 so that connector 10 has the approximate shape of a capital letter T. The lumens through first and second sections 12 and 14 communicate with one another inside the connector where the two sections meet.

30 In the particular embodiment shown in FIG. 1 connector 10 includes an open mesh framework 22 (e.g., a braid of nitinol, stainless steel, or tungsten wires or polymer strands) which may be covered with a rubber-

- 9 -

like web 24 (e.g., of silicone). Thus connector 10 may be constructed like various artificial grafts shown and described in the above-mentioned Goldsteen et al. reference. Indeed, many of the graft variations

5 described in the Goldsteen et al. reference are equally suitable for connector 10. Also in the particular embodiment shown in FIG. 1, first section 12 is of sufficient length that it actually forms an artificial graft structure. In other words, in this case first

10 section 12 is integral with an artificial graft structure. Alternatively, section 12 could be made shorter for tubular attachment to an initially separate artificial or natural graft. In general, references herein to attachment of a connector to a graft

15 structure will be understood to be generic to both (1) integral formation of the connector and graft structure, and (2) initially separate formation and subsequent joining of the connector and graft structure. If section 12 is initially separate from

20 the graft structure, it may be attached to the graft structure by inserting it coaxially in an end portion of the graft structure. Section 12 may then resiliently expand to annularly engage the end portion of the graft structure. In addition, section 12 may be

25 sutured to the graft structure. Or section 12 may have radially outwardly projecting prongs (which may be hooked and/or barbed) to improve engagement and retention of the graft structure by section 12. As still another possibility, section 12 may be crimped

30 around the outside of an axial end portion of the graft conduit as is described in more detail in connection with several later embodiments. Adhesive may also be used in connections between the connectors of this invention and the associated tubular conduits.

- 10 -

Additional information regarding various ones of these alternatives is provided in connection with other embodiments that are discussed below. In many cases the connector and graft conduit can be connected to one  
5 another in advance and outside the patient's body. This eliminates space constraints for suturing inside the body, and in the coronary area it also eliminates the complexity of suturing to a beating heart.

First and second sections 12 and 14 may be  
10 joined to one another in any of a variety of ways. For example, these two sections may be sutured together, welded together, or formed integrally. Particularly preferred joining techniques are shown in later FIGS. and described below.

15 An advantageous characteristic of the above-described connector structures (e.g., a nitinol framework covered by a silicone web) is that they are extremely elastic and resilient. Thus they can be radically deformed (e.g., during installation), and  
20 they thereafter return to their original shape without any damage or memory that they were deformed. This type of structure is also flexible in use so that it may advantageously pulse in response to blood pressure pulses when it is used in a patient's circulatory  
25 system. In other words, the connector is compliant under blood pressure.

In addition to showing illustrative connector 10, FIG. 1 shows part of illustrative apparatus 100 for installing a connector like  
30 connector 10 in a patient. The portion of apparatus 100 that is shown in FIG. 1 comprises delivery tube or sleeve 110. FIGS. 2 and 3 show progressive insertion of connector 10 into sleeve 110. In particular, one end portion of second section 14 is

- 11 -

inserted into sleeve 110 as shown in FIG. 2. Then first section 12 is folded down along the other end portion of second section 14 so that the remainder of connector 10 can be pushed into sleeve 110 as shown in  
5 FIG. 3.

Additional details regarding illustrative construction and use of apparatus 100 are shown in FIGS. 4-8. These FIGS. show apparatus 100 being used to install connector 10 through an aperture 34 in the  
10 side wall 32 of a patient's tubular body tissue structure 30 (e.g., a blood vessel). In particular, longitudinal guide structure 120 (e.g., a wire) is first inserted through aperture 34 into the lumen of body structure 30. Then a dilator structure 130 is  
15 advanced along and concentrically around guide structure 120 so that its distal, conically tapered, nose portion opens up aperture 34. The next step is to advance the distal portion of sleeve 110 over dilator 130, through dilated aperture 34, and into the  
20 lumen of body conduit 30 as shown progressively in FIGS. 4 and 5. Dilator structure 130 may then be withdrawn proximally as is also shown in FIG. 5 and ultimately removed from sleeve 110.

A subsequent step is shown in FIG. 6 and  
25 involves inserting connector 10 into and along sleeve 110 so that portions of connector 10 are disposed around guide structure 120. In particular, connector 10 may be initially inserted into the proximal end of sleeve 110 as shown in FIGS. 1-3, but  
30 with the addition of guide structure 120 passing through first section 12 and the end portion of section 14 that first section 12 is not folded back along.

- 12 -

When connector 10 has been pushed far enough along sleeve 110 so that all of second section 14 is inside the lumen of body conduit 30 as shown in FIG. 6, sleeve 110 can be pulled proximally as shown in FIG. 7. This leaves second section 14 disposed concentrically inside the lumen of conduit 30, with first section 12 extending part way out of aperture 34. Then, as shown in FIG. 8, first section 12 can be pulled back in the direction from which the connector was inserted. This shifts second section 14 along the lumen of conduit 30 until first section 12 is centered on aperture 34 and therefore extends out of the aperture with no remaining folding of the first section along second section 14. Connector 10 is now fully installed in conduit 30 and elements 110 and 120 can be removed if or when not needed for any further steps. Second section 14 resiliently expands when released from sleeve 110 to approximately the same size as the interior of body conduit 30. Thus second section 14 resiliently and annularly bears on the inner surface of the side wall 32 of conduit 30. This helps to secure connector 10 in conduit 30.

Illustrative, especially preferred, techniques for producing connectors 10 of the type shown in the previously described FIGS. are shown in FIGS. 9-12. In the embodiment shown in FIGS. 9-11 mesh framework strands 22 (one representative strand 22a being emphasized in FIG. 9 for purposes of illustration) that extend from an end of first section 12 as shown in FIG. 10 are woven or braided around cylindrical mandrel 210 as shown in FIG. 11 to produce the T-shaped finished connector framework shown in FIG. 9. In other words, first section 12 is formed first as shown in FIG. 10 with unbraided strands 22 of

- 13 -

the connector framework left extending from one end of that first section. Then these initially unbraided strands are used to weave or braid second section 14 around mandrel 210 as shown in FIG. 11. Thus in the finished connector framework shown in FIG. 9 framework strands 22 are unbroken and continuous between first and second sections 12 and 14 (as is apparent from considering representative strand 22a in FIG. 9).

In the alternative embodiment shown in FIG. 12 framework strands (e.g., emphasized strands 22b and 22c) that initially extend unbraided from an end of first section 12 are woven into the framework of second section 14. In other words, second section 14 is formed using framework strands 22 that are separate from the framework strands 22 that are used to form first section 12. However, the unbraided extensions of the first section strands are woven into the second section framework to unite the two sections as shown in FIG. 12.

FIG. 13 shows just one example of possible use of connectors of the type shown in the previously described FIGS. In this example, connector 10 is used to connect one end of a coronary bypass graft 220 to the coronary artery 30 of a patient downstream from a partial occlusion 36 of that artery. The other end of graft 220 is connected to an aperture in the side wall of the patient's aorta 40 (see FIGS. 36-39 and the discussion of those FIGS. below for an example of a connector that can be used to connect graft conduit 220 to an aperture in the side wall of much larger aorta 40). Second section 14 of connector 10 is disposed concentrically inside artery 30. First section 12 of connector 10 extends out of an aperture in the side wall of artery 30 and is connected to or

- 14 -

integral with graft 220. Accordingly, graft 220 and connector 10 cooperate to allow blood to flow from aorta 40 to artery 30 downstream from partial occlusion 36. This blood flow supplements the flow of blood through occlusion 36, thereby relieving the patient of the adverse effects of occlusion 36.

It may not be necessary in all cases for the connectors of this invention to have a full T shape. For example, FIG. 14 shows an illustrative use of a connector 10' in accordance with this invention in a bypass around a total occlusion 36' in a patient's coronary artery 30. Instead of being T-shaped, connector 10' is more nearly L-shaped. In other words, second section 14' of connector 10' extends transversely in only one direction from the adjacent end of first section 12'. In particular, second section 14' extends from first section 12' in the downstream direction in coronary artery 30. The upstream end of second section 14' can be closed or substantially closed because no blood is coming from that direction due to the presence of total occlusion 36'. In other respects the structures shown in FIG. 14 can be similar to what is shown in FIG. 13. If desired, connector 10' can be inserted in artery 30 (or any other tubular body conduit) in substantially the same way that connector 10 is inserted (e.g., using apparatus of the type shown in FIGS. 1-8). The only difference is that in the case of connector 10', second section 14' extends in only one direction along conduit 30 from aperture 34.

FIG. 14a shows an alternative installation of an L-shaped connector 10". As in earlier embodiments, connector 10" can be initially separate from or integral with graft vessel 220". For example, the



- 15 -

design may utilize shape memory braid over a tapered and formed mandrel, and may be shaped to match the inner lumen size of the grafted vessel and tapered to transition from the aortic connection to the inner  
5 lumen dimension.

As will be appreciated from the foregoing, the connectors and connector insertion apparatus of this invention are suitable for use in conventional surgery and in less invasive patient treatment  
10 procedures such as percutaneous laparoscopy and intraluminal procedures of the kind described in the first three references mentioned above. If the target body conduit 30 has been exposed surgically, apparatus 100 can be made to approach the body conduit  
15 through the surgical opening. With regard to laparoscopic or intraluminal procedures, the connectors of this invention have (or can be folded to have) relatively small cross sections. Apparatus 100 can also have a small cross section. This allows the  
20 connector and associated apparatus 100 to be inserted into the patient via the relatively small passageways or instruments that are used for laparoscopy. Similarly, such small cross sections allow the connector and associated apparatus 100 to be inserted  
25 into the patient intraluminally.

FIG. 15 shows another illustrative T-shaped connector 310 in accordance with the invention. Connector 310 includes a first section 312 which is adapted to be received in an end of a tubular graft  
30 320. Connector 310 also includes a second section 314 which initially has a relatively small cross section as shown in FIG. 15, but which is circumferentially enlargeable to a relatively large cross section as shown in FIGS. 16 and 17. For example, second

- 16 -

section 314 may be a modified (e.g., perforated) metal tube which is circumferentially expandable by a selectively inflatable balloon inside that section. Connector 310 is typically inserted into a patient's tubular body conduit 30 with second section 314 in its relatively small cross-sectional configuration. Then second section 314 is circumferentially expanded so that it annularly engages the inner surface of the side wall 32 of the conduit 30. Graft conduit 320 (which, as in other embodiments, may be artificial conduit, natural conduit, or a combination of both) may be attached to first section 312 before or after second section 314 is inserted in conduit 30. An annular external seal 350 (FIG. 17) can be applied over the connector around aperture 34 to provide a hemodynamic seal and to promote in-growth of tissue to further reinforce vessel connection over time. Examples of materials suitable for use in making seal 350 are silicone and urethane.

Another illustrative T-shaped connector 410 is shown in FIG. 18. Connector 410 includes a first section 412 that may be a tubular framework. Connector 410 also includes a second section 414 that comprises spring coils that extend transversely from an end portion of first section 412. Sections 412 and 414 may be made of shape memory materials similar to those mentioned above for the framework of sections 12 and 14 in FIG. 1. Second section 414 is axially compressible as shown in FIG. 19 to facilitate insertion of the second section through an aperture 34 in a side wall of a patient's tubular body conduit 30. After second section 414 has been inserted through aperture 34 in the axially compressed condition shown in FIG. 19, the axial compression of the second section is released so

- 17 -

that the second section can spring back to its original condition but inside the lumen of conduit 30 as shown in FIG. 20. Graft conduit 420 may be artificial, natural, or both, and may be attached to first section 412 (e.g., by suturing) at any convenient time either before or after insertion of second section 414 in conduit 30. First section 412 may be inserted into an axial end portion of graft conduit 420 and allowed to resiliently expand into annular engagement with that end portion. Or first section 412 may be crimped around the outside of the end portion of graft conduit 420. Protrusions from first section 412 may penetrate the end portion of conduit 420 to more securely attach these two structures. These protrusions may be hooked and or barbed for even better retention of conduit 420. Some of these alternatives are discussed in more detail in connection with subsequently described embodiments. If desired, an annular seal 450 (similar to above-described seal 350) may be placed around the outside of the joint between graft 420 and conduit 30 as shown in FIGS. 21 and 22 for purposes similar to those described above for seal 350. Although all of the connectors of this invention facilitate and thereby speed up the making of graft connections, embodiments like the one shown in FIGS. 18-22 are particularly quick to install. Embodiments of this kind therefore have especially "quick-connect" characteristics.

Rather than being just a single spring coil as shown in FIGS. 18-22, more complex spring shapes can be used for second section 414, one example being shown at 514 in FIGS. 23-25. Illustrative constructions of section 514 include a resilient, axially compressible spring braid or a self-expanding nitinol tube. The second section is axially compressed as shown in

- 18 -

FIG. 23 to facilitate insertion of the second section through aperture 34 in the side wall of body conduit 30. After second section 514 is through aperture 34, the axial compression of the second section is released so that it springs out along the lumen of conduit 30 as shown in FIGS. 24 and 25. Section 514 may have a rubber-like (e.g., silicone) outer cover to prevent leakage via aperture 34 around first section 512.

FIG. 25 illustrates another possible constructional feature of the connectors of this invention. This is a circumferentially crimpable first section 512 (e.g., of nitinol or stainless steel). In particular, crimpable first section 512 has an initially relatively large circumference into which an end of tubular graft 520 can be inserted. First section 512 is then circumferentially crimped to reduce its circumference and cause it to annularly engage the outside of graft conduit 520. The inner surface of first section 512 may have radially inwardly extending prongs 560 (e.g., of nitinol or stainless steel) to penetrate or at least deform the material of graft conduit 520 and thereby help to retain the graft conduit in the first section. Prongs 560 may be hooked (i.e., curved) and/or barbed (somewhat like fishhooks) to still further strengthen the connection between graft conduit 520 and connector 510. Adhesive may also be used to further secure the connector to graft conduit 520. It may be advantageous to secure the connector to the outside of the graft conduit in this general way because it reduces possible obstruction of fluid flow in the graft conduit due to the presence of the connector. In the case of natural graft conduits, securing the connector to the outside of that conduit

- 19 -

helps protect the delicate internal lumen of the conduit.

FIG. 26 shows that crimpable first section 512 may initially have an axially extending gap 562 in its side wall. After graft conduit 520 has been inserted in first section 512, gap 562 is closed (e.g., by use of a crimping tool 570 as shown in FIG. 28). Closing gap 562 allows latching elements 564a and 564b on respective opposite sides of the gap to interengage and latch as shown in FIG. 27, thereby holding the gap closed. A mandrel 580 may be placed inside graft conduit 520 during operation of crimping tool 570 to ensure that first section 512 and its prongs 560 (if any) properly engage the graft conduit. As an alternative to crimping by closing a gap, a crimpable connector section may be made of a crimpable material or some other crimpable structure. For example, a split and overlapping ring structure may be used as shown in FIG. 39 and described in more detail below.

It should be mentioned that various sections of the connectors of this invention do not have to be circular in cross section. For example, the first section of a connector can have an oval cross section if desired. This may be useful, for example, when it is necessary to connect an end of a relatively large graft conduit to the side wall of a somewhat smaller conduit 30. FIG. 29 shows an example of an oval crimp-type connector or connector portion 612. As in the embodiments illustrated by FIGS. 25-28, connector portion 612 is crimped around the outside of graft conduit 620 and has radially inwardly extending prongs 660 for penetrating the material of the graft conduit to more securely engage that conduit.

- 20 -

FIGS. 30-32 show application of certain of the principles of this invention to end-to-end connectors. In particular, connector 710 is to be used to connect an end of vessel 730a to an end of vessel 730b. For example, one of these vessels may be a tubular graft conduit. Connector 710 includes two axially aligned tubular end sections 712a and 712b joined by an intermediate tubular seal section 750. Each of end sections 712 is circumferentially crimpable to annularly engage the outer surface of the end of a respective one of vessels 730 which has been inserted in that end section (see FIG. 32). Prongs 760 extend radially inwardly from each of end sections 712 as shown in FIG. 31 to better hold the associated vessel in that end section. Seal section 750 (e.g., of silicone or urethane) prevents leakage from the ends of the vessels 730 that have been joined by the connector.

An alternative embodiment of an end-to-end connector 810 is shown in FIGS. 33-35. Connector 810 is similar to connector 710, except that seal section 850 (again, e.g., of silicone or urethane) is axially compressible. Thus after the ends of vessels 830a and 830b are inserted into connector sections 812a and 812b, and those connector sections are crimped around the vessel ends, sections 812a and 812b are forced toward one another to axially compress seal section 850. This helps bring the ends of vessels 830a and 830b together inside the connector. If vessels 830a and 830b are both natural tissue, bringing their ends together helps to promote healing between the vessel ends.

Another illustrative application of the crimpable connector technology of this invention is shown in FIGS. 36-39. Connector 910 is shown by itself

- 21 -

prior to crimping and installation in FIG. 36.

Connector 910 includes crimpable tubular section 912 which has resilient struts 970 (e.g., of nitinol wire) that extend radially out from both of its axial ends.

5 Connector 910 illustrates an alternative crimpable structure in which section 912 is an axially slit tube with the slit edge portions radially overlapping one another (see also FIG. 39). This structure is crimped to reduce its initially relatively large circumference  
10 by increasing the amount of overlap of the slit edge portions. This principle is applicable to any of the crimpable connector structures shown and described herein.

To use connector 910 the end portion of a  
15 conduit 920 to be connected to an aperture 934 in the side wall 932 of another conduit 930 is inserted in section 912 and section 912 is crimped around that end portion of conduit 920 as shown in FIG. 37. For example, conduit 920 may be a graft conduit which is to  
20 be connected to a patient's body conduit 930.

Prongs 960 extend into the side wall of conduit 920 as in related previously described embodiments. Struts 970 are deflected substantially parallel to the longitudinal axis of conduit 920. This may be done,  
25 for example, by surrounding the structure shown in FIG. 37 with a delivery tube (not shown). In the condition shown in FIG. 37 connector 910 is installed in aperture 934 and struts 970 are released so that they can resiliently spring out and resume their initial  
30 positions as shown in FIGS. 38 and 39. By extending radially out from section 912, struts 970 bear on both the inner and outer surfaces of conduit side wall 932. Struts 970 thereby hold connector 910 and conduit 920 in the position required to connect conduit 920 to

- 22 -

conduit 930. Connectors of the type shown in FIGS. 36-39 are particularly suitable for connecting an end of a relatively small conduit 920 to the side wall of a relatively large conduit 930. For example, a connector of this type can be used in FIGS. 13-14a to connect the upstream end of graft conduit 220 or 220" to aorta 40.

FIGS. 40 and 41 show another illustrative embodiment of an L-shaped connector 1010 in accordance with this invention. Connector 1010 may be braided or coiled strands of nitinol, stainless steel, tungsten, or polymer, or nitinol tubing, as in other previously described embodiments. Connector 1010 includes a first section 1012 which may be crimpable around an end portion of tabular conduit 1020 as in related previously described embodiments. Alternatively or in addition, first section 1012 may include hooks and/or barbs for connection to conduit 1020. Second section 1014 extends transversely from first section 1012 in only one direction and is configured to extend along the lumen inside another tubular conduit (not shown). To help hold second section 1014 in the other conduit, the second section may have a plurality of radially outwardly extending prongs 1080 (e.g., of nitinol wire) that deform or penetrate the side wall of the conduit in which the second section is disposed. Prongs 1080 may be curved and/or barbed somewhat like fishing hooks to help them even more securely hold onto the tissue that they engage. Either or both sections 1012 and 1014 of connector 1010 may be balloon-expanded to help anchor that section to the associated conduit

FIGS. 42 and 43 show another illustrative embodiment of a T-shaped connector 1110 which can be somewhat like the embodiment shown in FIGS. 15-17. The principal difference between this embodiment and the



- 23 -

FIGS. 15-17 embodiment is that in connector 1110 the second section 1114 of the connector extends only part of the way around the inside of body conduit 30. This reduces the amount of connector material that is in  
5 contact with the interior surface of conduit 30. Reducing the circumferential extent of second section 1114 in this way may also facilitate delivery and installation of the connector. Second section 1114 may be perforated to facilitate changes of shape of that  
10 section for deployment of the connector. Graft conduit 1120 may be attached to first section 1112 in any suitable way (e.g., as described above in connection with other embodiments).

It will be understood that the forgoing is  
15 only illustrative of the principles of the invention, and that various modifications can be made by those skilled in the art without departing from the scope and spirit of the invention. For example, although particular materials have been mentioned for various  
20 components of the connectors of this invention, other materials can be used instead if desired.

- 24 -

The Invention Claimed Is

1. A connector for making a tubular connection between first and second tubular structures in a patient comprising:

a first section configured to make a tubular connection to the first tubular structure; and

a second section transverse to a longitudinal axis of the first section and configured to make a tubular connection to the second tubular structure.

2. The connector defined in claim 1 wherein the second section is tubularly connected to the first section.

3. The connector defined in claim 1 wherein the second section extends transversely in two opposite directions from the longitudinal axis of the first section.

4. The connector defined in claim 1 wherein the second section is configured to extend along the interior of the second tubular structure.

5. The connector defined in claim 4 wherein the second section is configured to extend in diametrically opposite directions along the interior of the second tubular structure from an aperture in a side wall of the second tubular structure, the first section being configured to pass through the aperture.

6. The connector defined in claim 5 wherein the second section is configured to extend only part

- 25 -

way around a circumference of the interior of the second tubular body structure.

7. The connector defined in claim 5 wherein the second section is configured to extend all the way around a circumference of the interior of the second tubular body structure.

8. The connector defined in claim 1 wherein the second section is configured to extend through an aperture in a side wall of the second tubular structure and substantially coaxially along the interior of the second tubular structure from the aperture.

9. The connector defined in claim 1 wherein the first section is configured for substantially coaxial tubular connection to an end portion of the first tubular structure.

10. The connector defined in claim 9 wherein the first section is configured for insertion inside the end portion.

11. The connector defined in claim 9 wherein the first section is configured to receive the end portion inside the first section.

12. The connector defined in claim 8 wherein the second section is configured to resiliently circumferentially expand to annularly engage surrounding second tubular structure.

13. The connector defined in claim 10 wherein the first section is configured to resiliently

- 26 -

circumferentially expand to annularly engage surrounding first tubular structure.

14. The connector defined in claim 8 wherein the second section is radially expandable to annularly engage surrounding second tubular structure.

15. The connector defined in claim 11 wherein the first section is circumferentially compressible to annularly engage the end portion inside the first section.

16. The connector defined in claim 1 wherein at least one of said sections includes:

radially extending members configured to engage adjacent tubular structure.

17. The connector defined in claim 16 wherein the radially extending members are configured to penetrate the adjacent tubular structure.

18. The connector defined in claim 16 wherein the at least one of said sections is configured for insertion into the adjacent tubular structure, and wherein the members extend radially out from the at least one of said sections.

19. The connector defined in claim 16 wherein the at least one of said sections is configured to receive the adjacent tubular structure coaxially inside the at least one of said sections, and wherein the members extend radially in from the at least one of said sections.

- 27 -

20. The connector defined in claim 8 further comprising:

an annular seal around the connector where the connector passes through the aperture for helping to seal the aperture to the connector.

21. The connector defined in claim 1 wherein the first section comprises a framework of connector material, and wherein strands extending from an end of the first section are formed into a framework for the second section.

22. The connector defined in claim 1 wherein each of the first and second sections comprises a framework of connector material, and wherein strands extending from an end of the first section are woven into the framework of the second section.

23. Apparatus inserting a connector through an aperture in a side wall of a patient's tubular body structure so that a second tubular structure can be tubularly connected to the tubular body structure comprising:

a longitudinal member configured to extend through the aperture and along the tubular body structure;

a dilator movable axially along the longitudinal member and configured to enlarge the aperture; and

a tube movable axially along the longitudinal member relative to the dilator and configured to pass through the aperture enlarged by the dilator.

- 28 -

24. The apparatus defined in claim 23 wherein the tube is configured to substantially coaxially receive the tubular connector for axial movement along the interior of the tube in order to deposit a second section of the connector substantially coaxially inside the tubular body structure with a first section of the connector extending out of the aperture.

25. The apparatus defined in claim 24 wherein the longitudinal member is configured for the tubular connector to substantially coaxially surround the longitudinal member.

26. The method of installing a tubular connector in a patient's tubular body structure through an aperture in a side wall of the tubular body structure comprising the steps of:

deploying a longitudinal member so that it extends through the aperture and along the tubular body structure;

moving a dilator along the longitudinal member so that the dilator enlarges the aperture;

inserting a tube through the aperture enlarged by the dilator;

passing the connector substantially coaxially along the tube so that a second section of the connector extends substantially coaxially along the interior of the tubular body structure and a first section of the connector extends out of the tubular body structure via the aperture.

- 29 -

27. The method defined in claim 26 wherein the moving causes the dilator to enter the aperture from outside the tubular body structure.

28. The method defined in claim 26 wherein the inserting causes the tube to enter the aperture from outside the tubular body structure.

29. The method defined in claim 26 where the passing causes the connector to enter the tubular body structure from outside the tubular body structure.

30. The method defined in claim 28 further comprising:  
    withdrawing the tube from the aperture after the passing.

31. The method defined in claim 26 further comprising:  
    removing the dilator from the aperture after the inserting.

32. A structure for attachment to a tubular conduit for use in making a tubular connection to another conduit in a patient comprising:

    a substantially annular component having an initially relatively large circumference as compared to the circumference of the tubular conduit so that an axial portion of the tubular conduit can be inserted substantially coaxially into the annular component, the annular component being annularly compressible to a relatively small circumference, in which condition the annular component can substantially annularly engage

- 30 -

the axial portion of the tubular conduit that has been inserted in the annular component.

33. The structure defined in claim 32 further comprising a plurality of prongs extending radially inwardly from the annular component.

34. The structure defined in claim 33 wherein the prongs are configured to penetrate the axial portion of the tubular conduit that has been inserted in the annular component when the annular component is compressed to the relatively small circumference.

35. The structure defined in claim 32 wherein the annular component comprises:  
axial portions that overlap one another in the radial direction, the extent of said axial portions increasing in the circumferential direction when the annular component is compressed to the relatively small circumference.

36. The structure defined in claim 32 wherein the annular component comprises:  
initially circumferentially spaced latching elements for latching together and holding the annular component in the relatively small circumference after the annular component has been compressed to the relatively small circumference.

37. The structure defined in claim 32 further comprising:  
an attachment structure connected adjacent an axial end of the annular component and



- 31 -

configured to attach the annular component to the other conduit.

38. The structure defined in claim 37 wherein the attachment structure is configured for insertion into a lumen of the other conduit through an aperture in a side wall of the other conduit.

39. The structure defined in claim 38 wherein the attachment structure comprises a plurality of resilient fingers that are resiliently biased to extend radially out from the annular component.

40. The structure defined in claim 39 further comprising a second plurality of resilient fingers that are resiliently biased to extend radially out from the annular component, the second plurality of resilient fingers being axially spaced from the previously defined fingers so that the fingers in the second plurality remain outside the other conduit when the previously defined fingers are inside the lumen of the other conduit.

41. The structure defined in claim 38 wherein the attachment structure includes a tubular portion configured to be substantially coaxially disposed in the lumen of the other conduit.

42. The structure defined in claim 41 wherein the tubular portion extends transverse to a longitudinal axis of the annular component.

43. The structure defined in claim 42 wherein the tubular portion includes first and second

- 32 -

tubular subportions which extends in diametrically opposite directions along an axis which is transverse to the longitudinal axis of the annular component.

44. The structure defined in claim 37 wherein the attachment structure is configured for attachment to an end portion of the other conduit.

45. The structure defined in claim 44 wherein the attachment structure comprises a second substantially annular component which is substantially coaxial with the annular component.

46. The structure defined in claim 45 wherein the second annular component has an initially relatively large circumference as compared to the circumference of the other conduit so that an axial portion of the other conduit can be inserted substantially coaxially into the second annular component, the second annular component being annularly compressible to a relatively small circumference, in which condition the second annular component can substantially annularly engage the axial portion of the other conduit that has been inserted in the second annular component.

47. The structure defined in claim 46 further comprising a plurality of prongs extending radially inwardly from the second annular component.

48. The structure defined in claim 47 wherein the prongs are configured to penetrate the axial portion of the other conduit that has been inserted in the second annular component when the

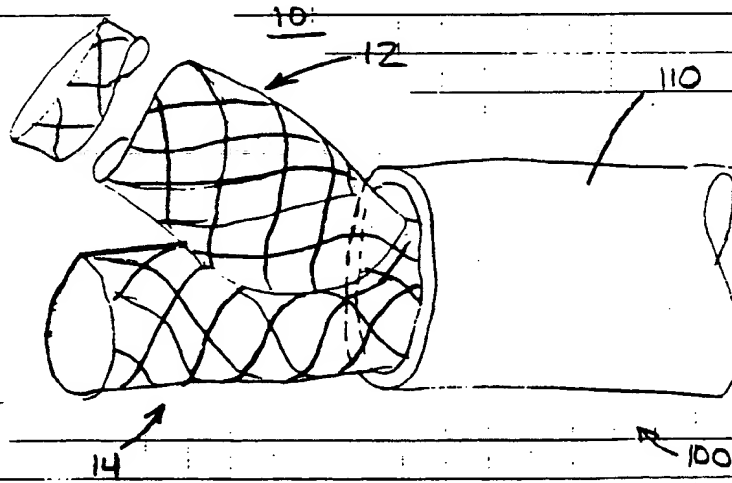
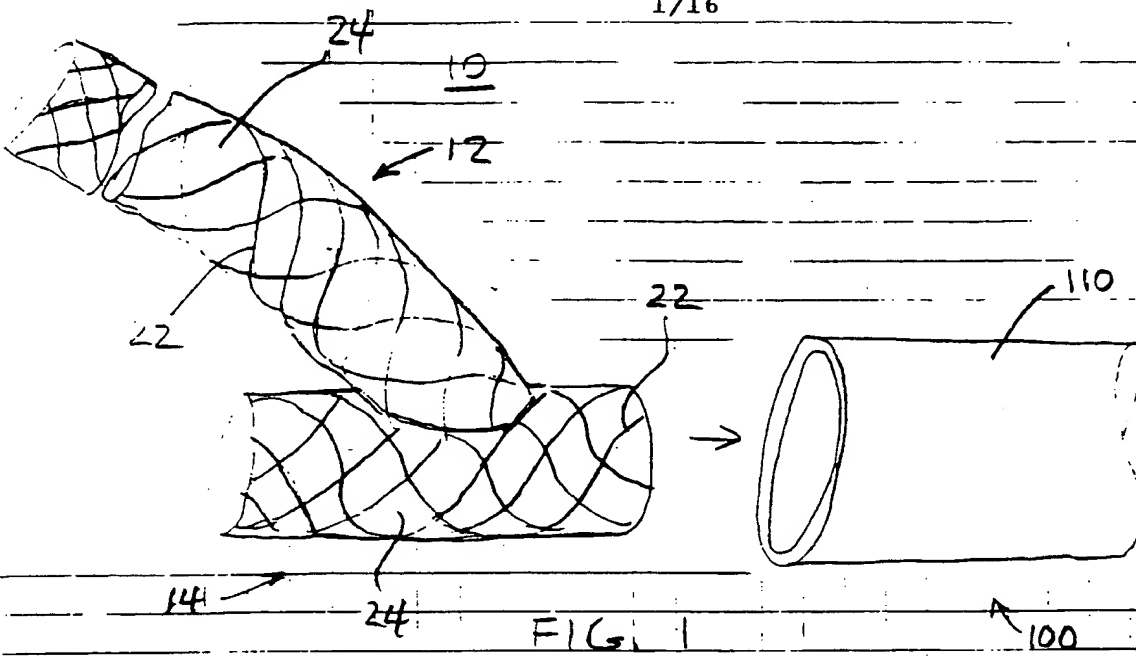
- 33 -

second annular component is compressed to the relatively small circumference.

49. The structure defined in claim 46 further comprising:

an axially compressible, tubular link between the annular component and the second annular component, the tubular link being substantially coaxial with the annular component and the second annular component.

1/16



27/16

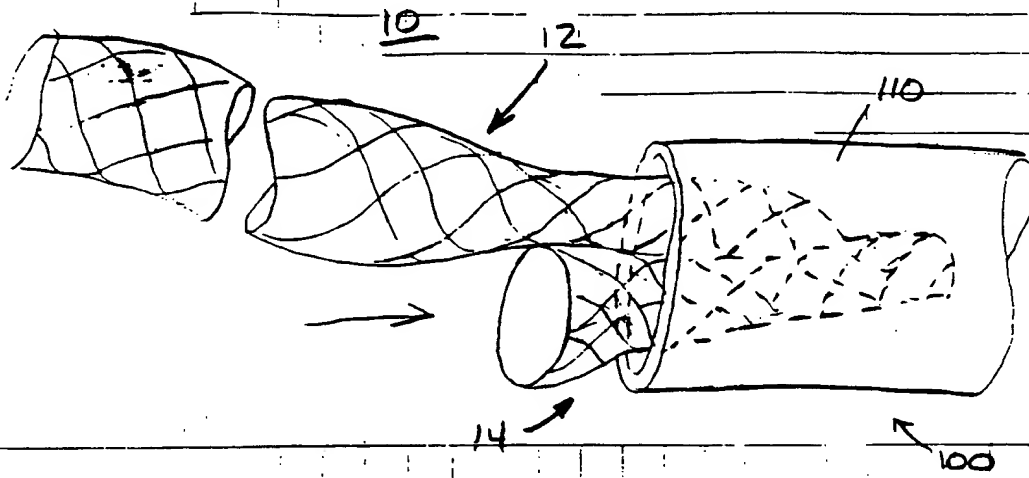


FIG. 3

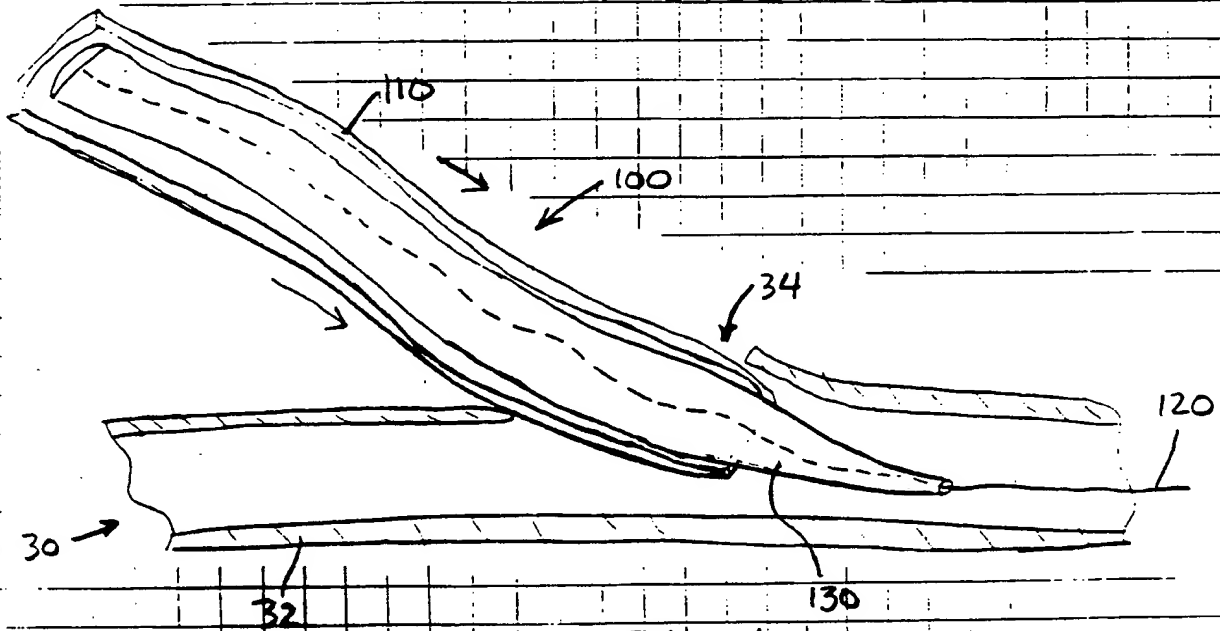


FIG. 4

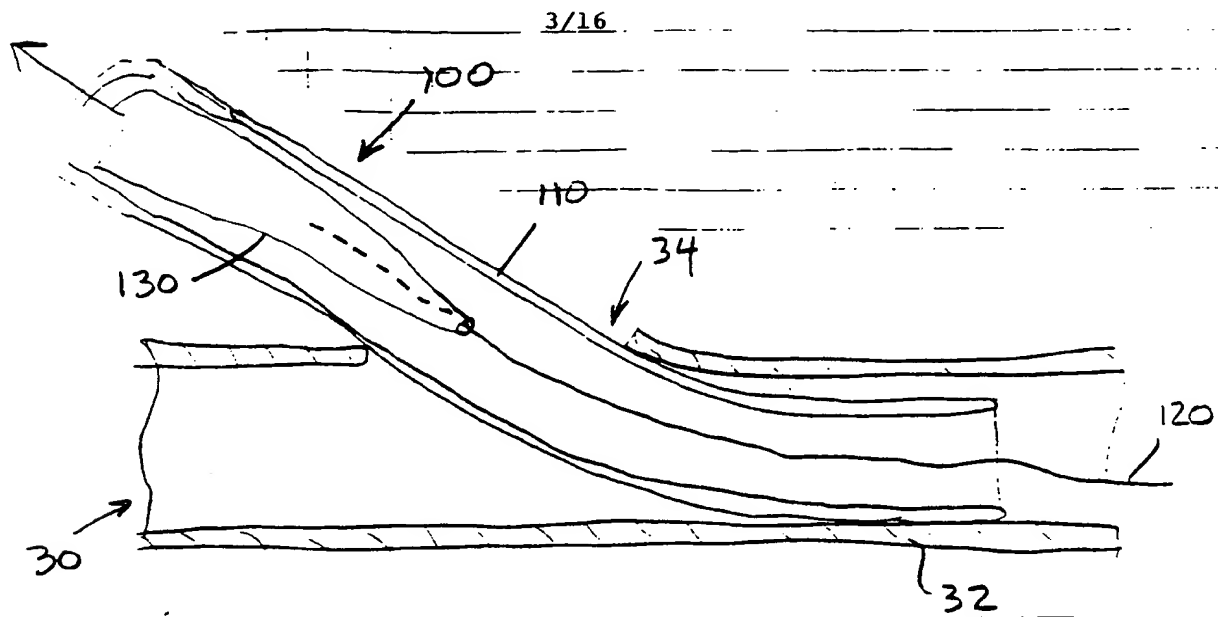


FIG. 5

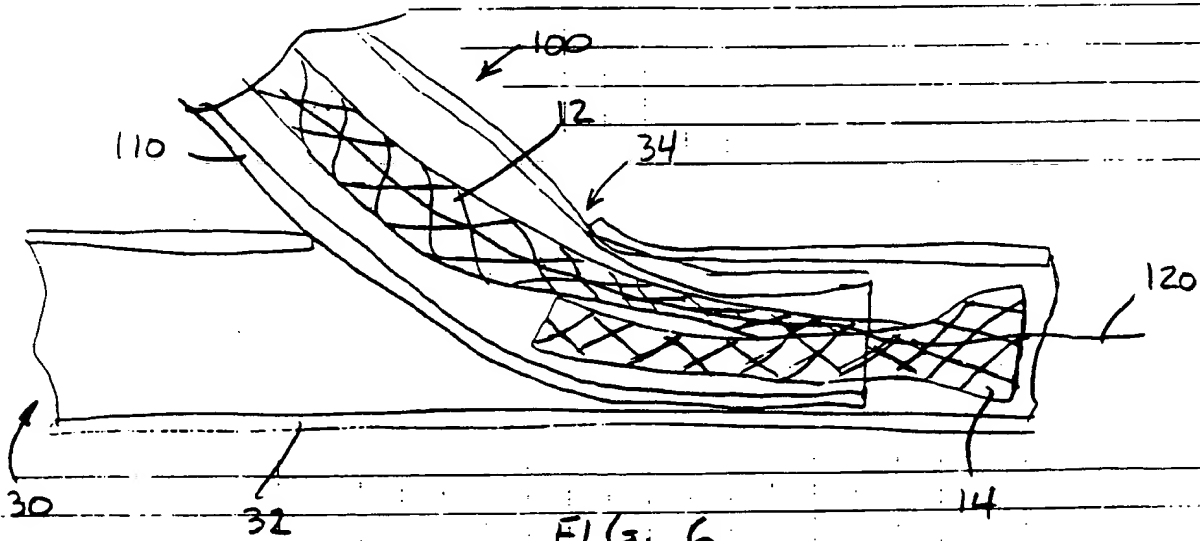
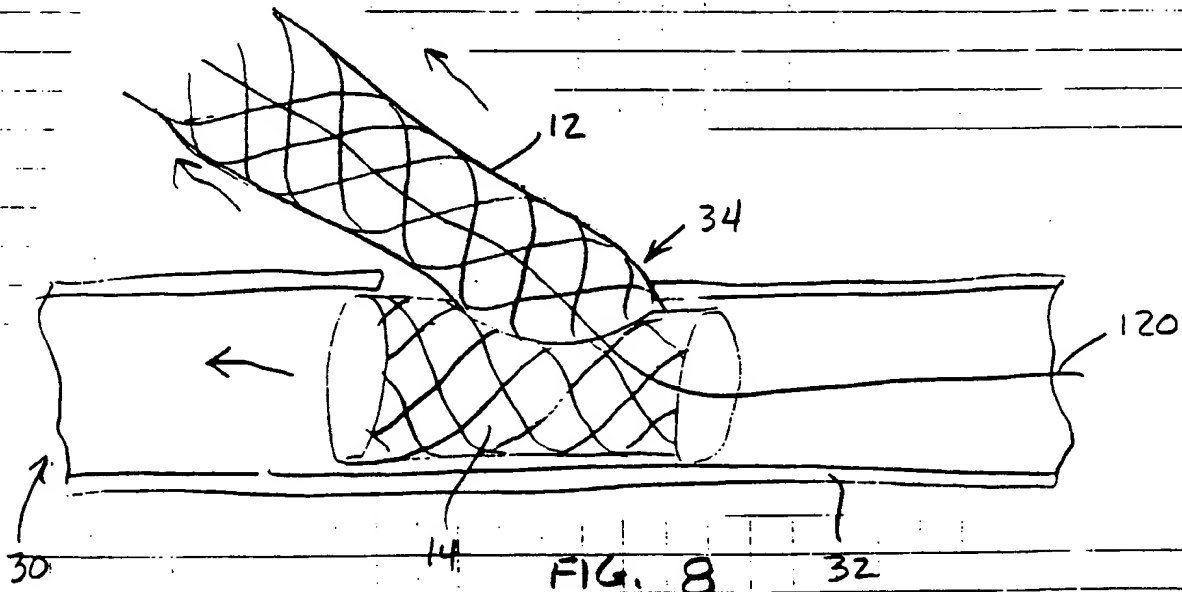
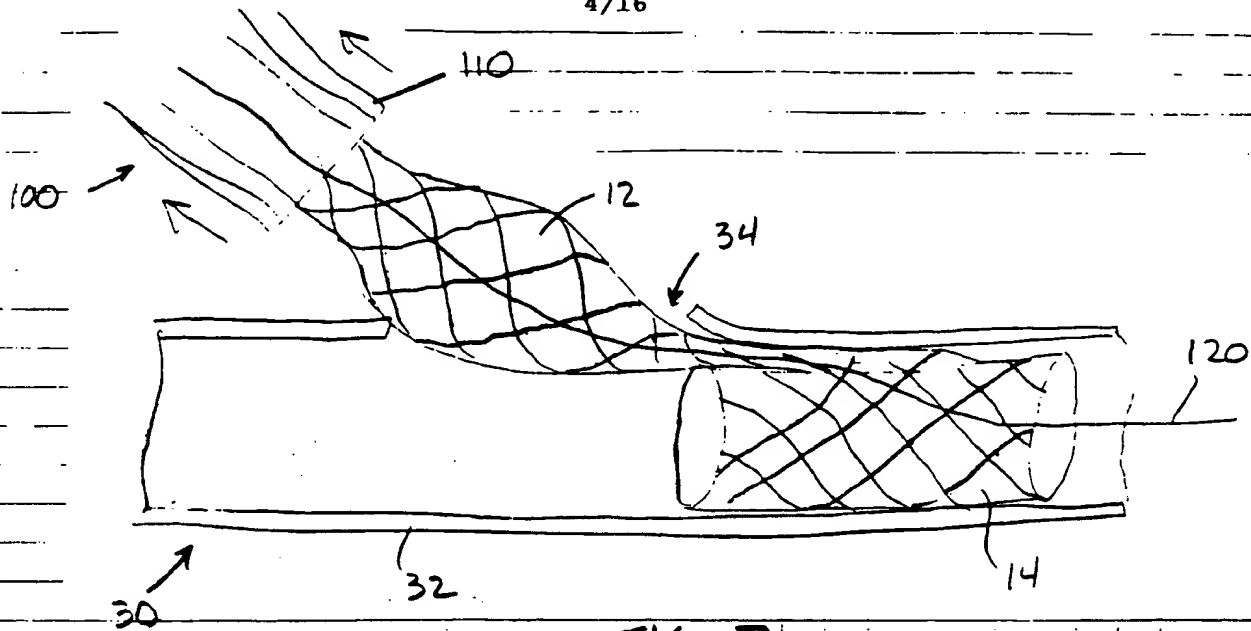


FIG. 6

4/16



5/16

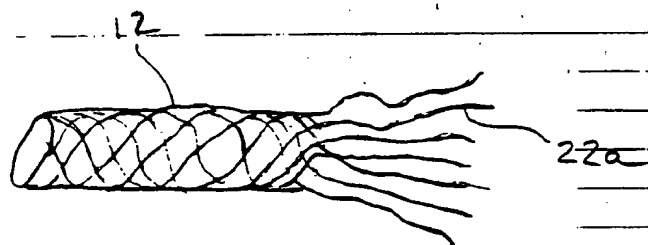
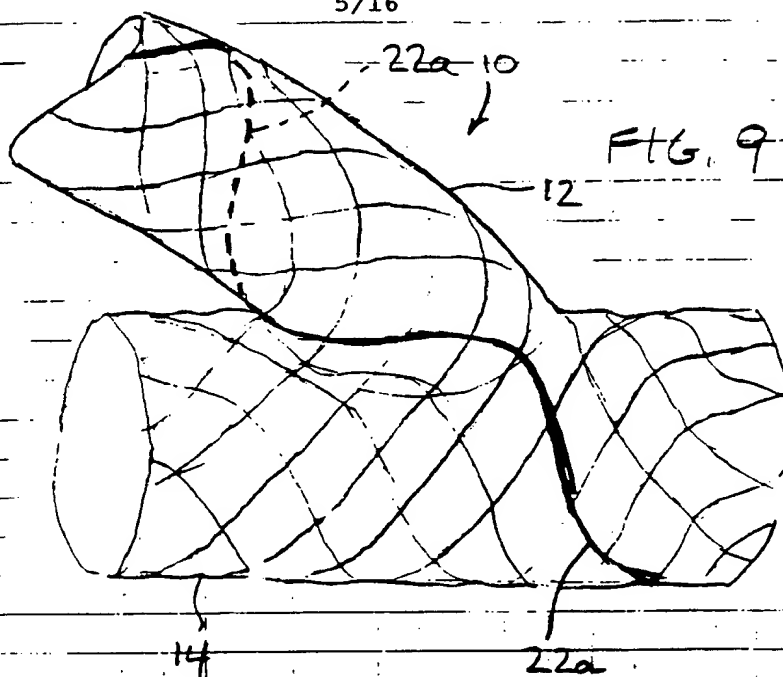


FIG. 10

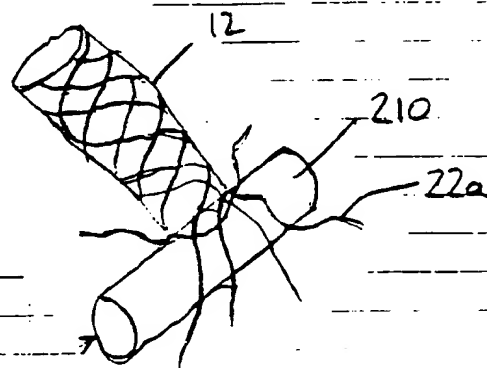
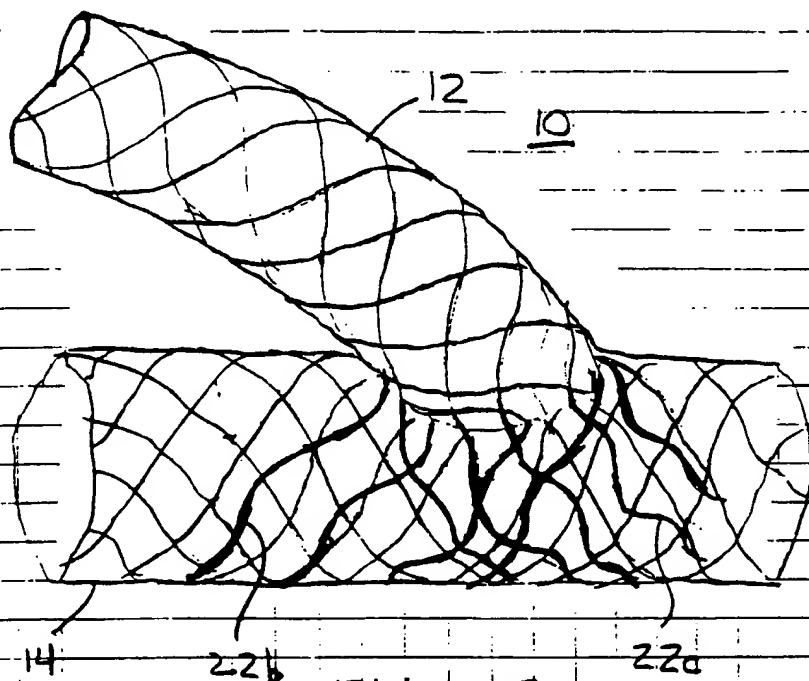


FIG. 11



6/16



7/16

FIG. 13

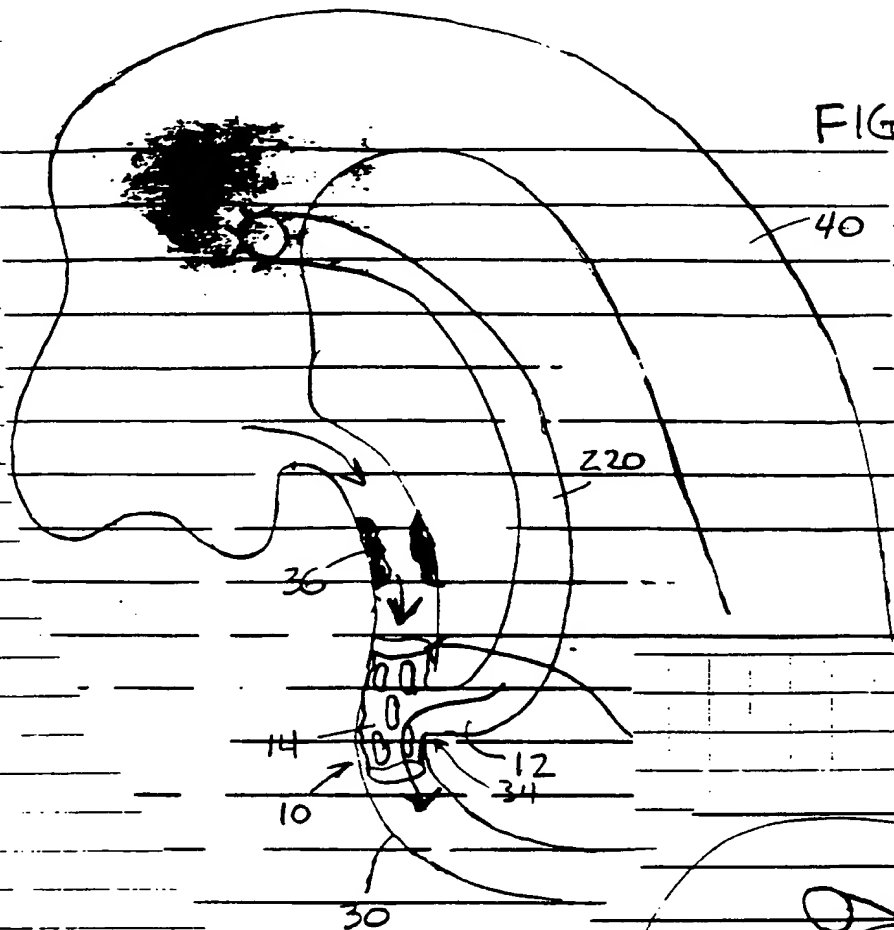
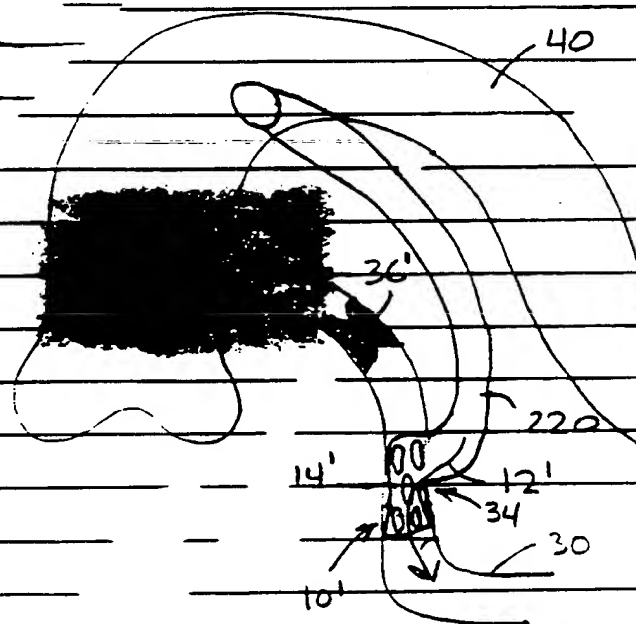


FIG. 14



8/16

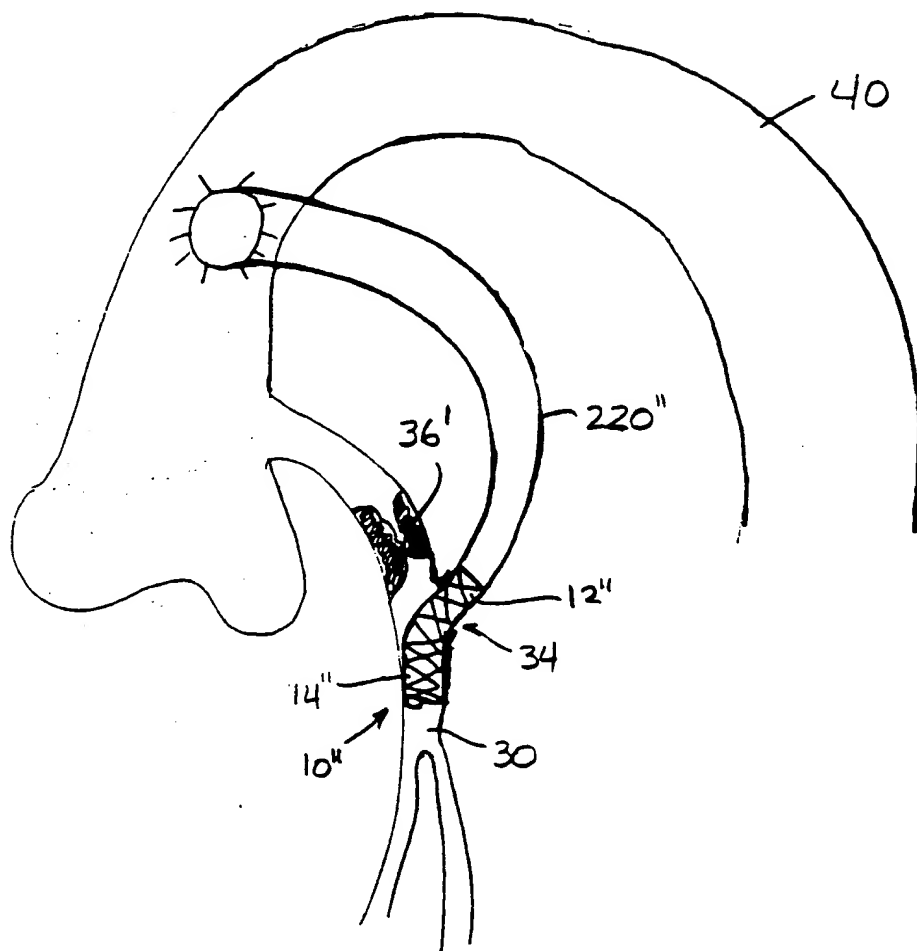


FIG. 14a

9/16

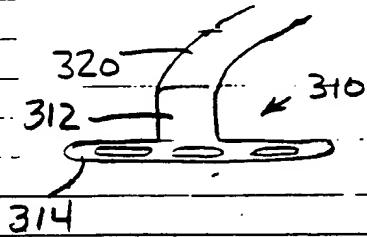


FIG. 15

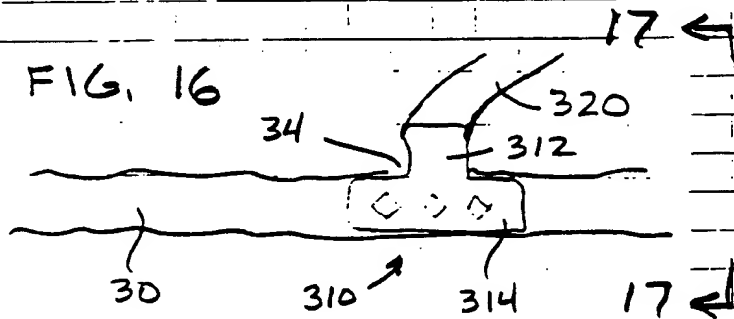


FIG. 16

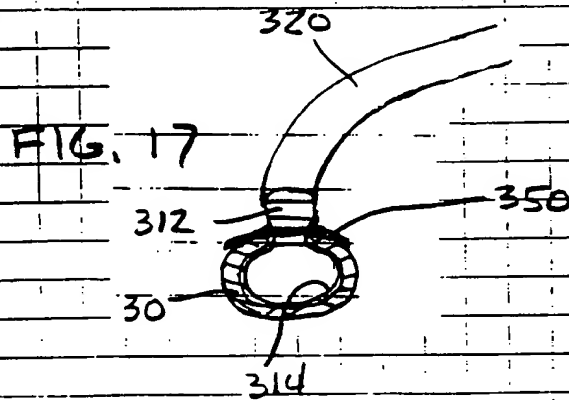


FIG. 17

10/16

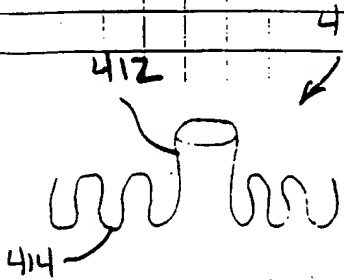


FIG. 18

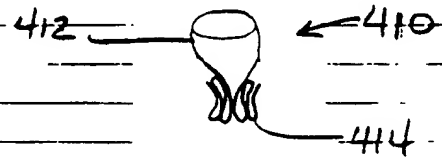


FIG. 19

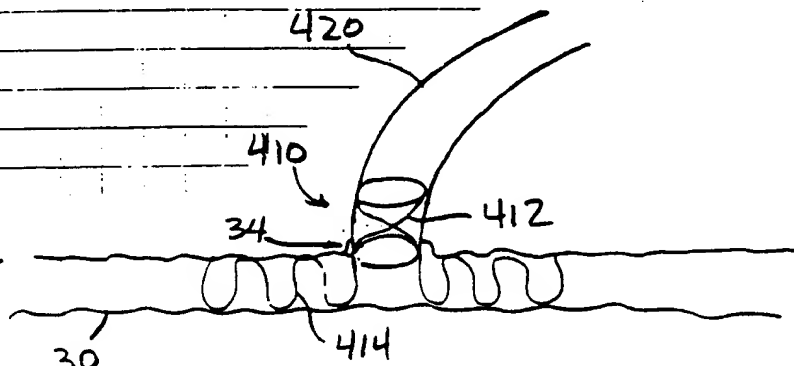


FIG. 20

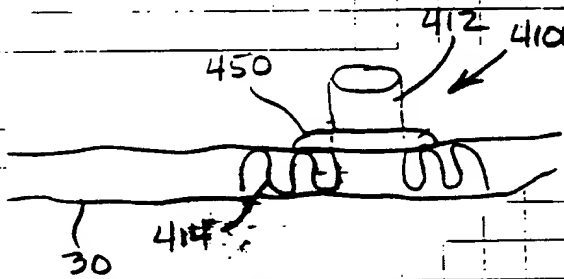


FIG. 21

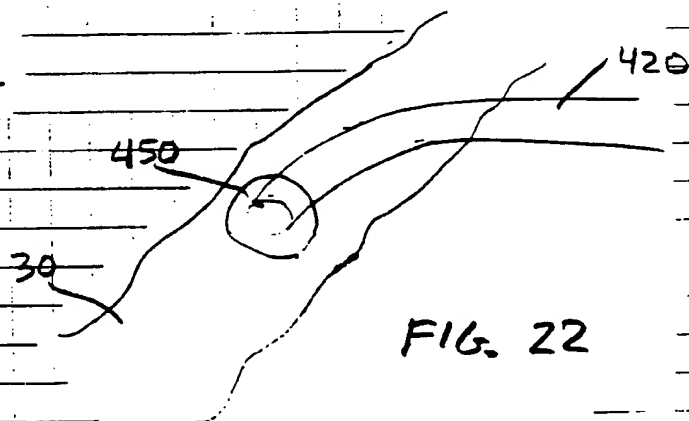


FIG. 22

11/16

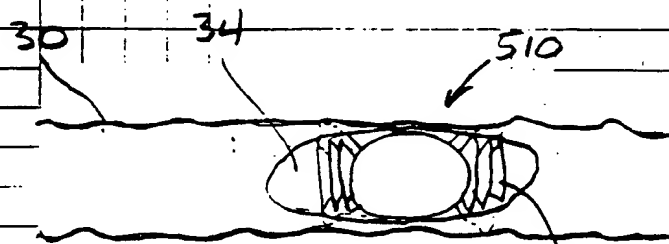


FIG. 23 514

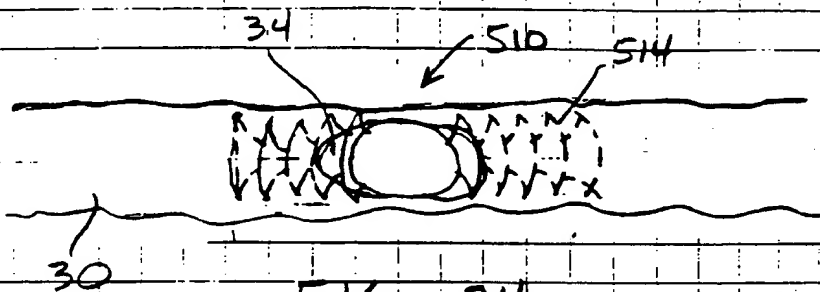


FIG. 24

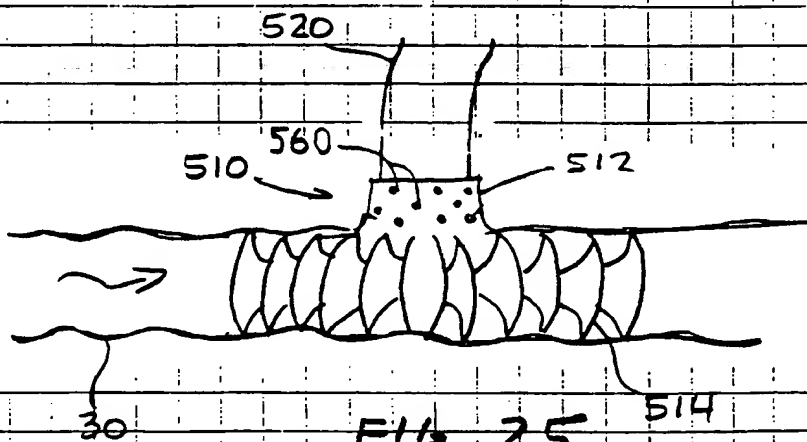


FIG. 25 514

12/16

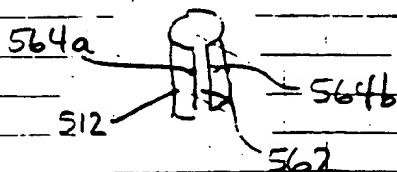


FIG. 26

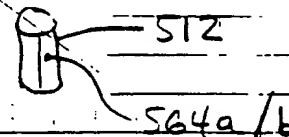


FIG. 27

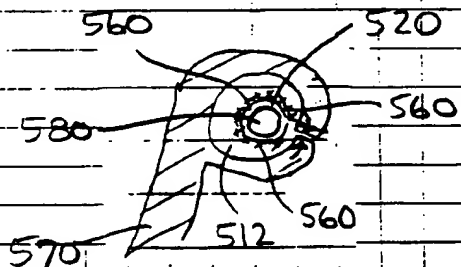


FIG. 28

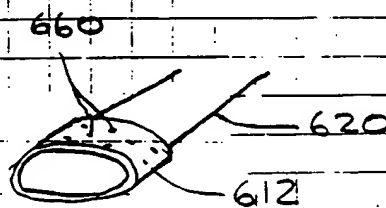
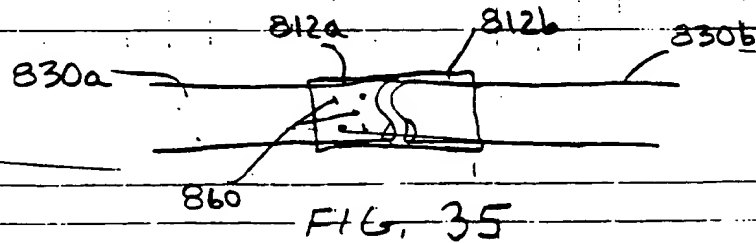
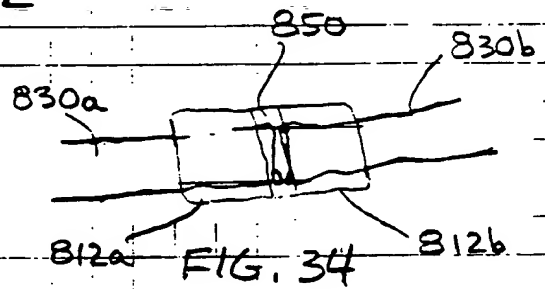
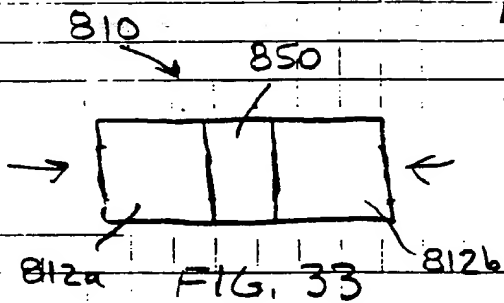
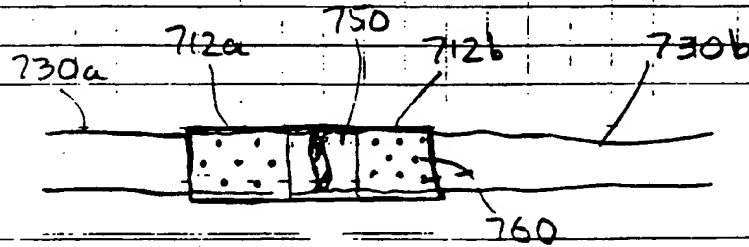
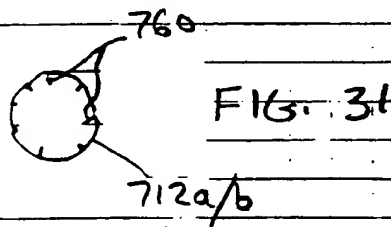
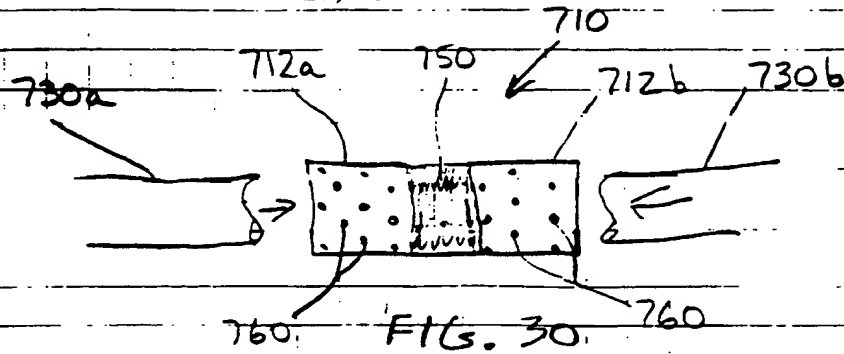


FIG. 29

13/16





14/16

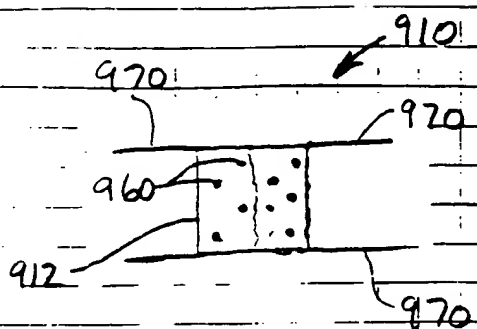


FIG. 36

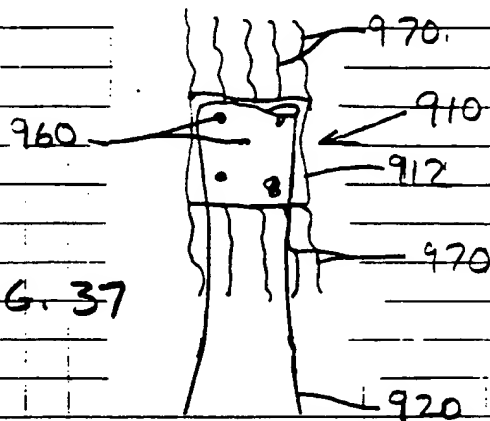


FIG. 37

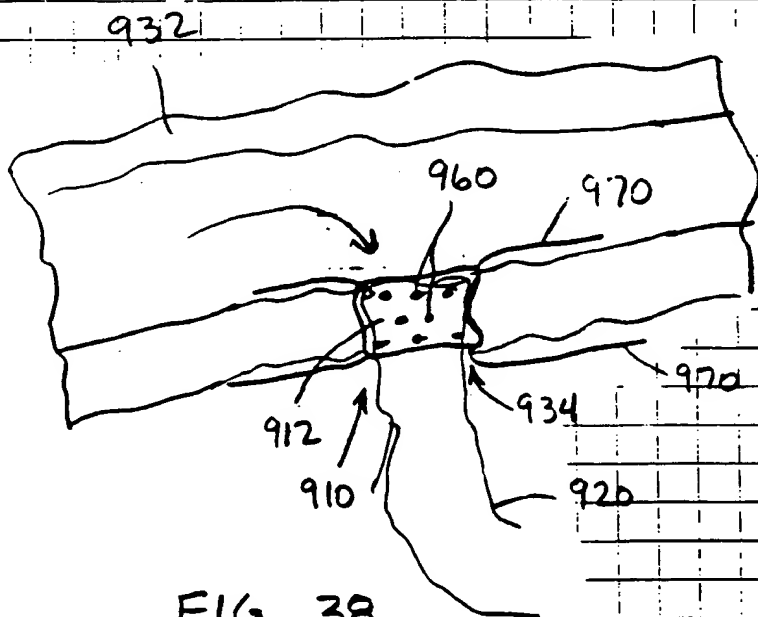


FIG. 38

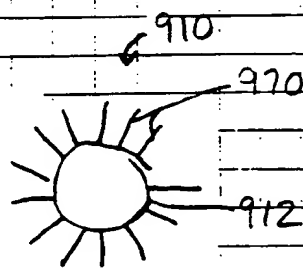
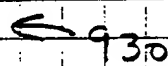


FIG. 39

15/16

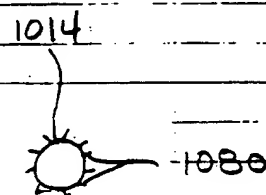
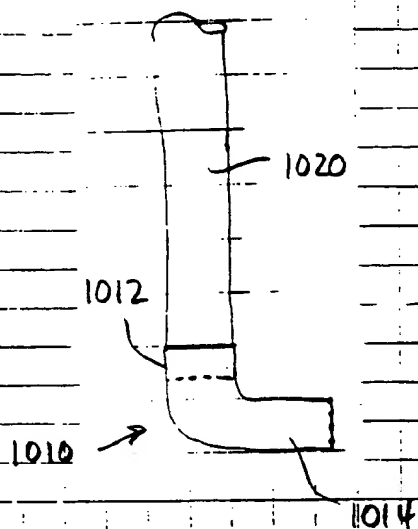


FIG. 42

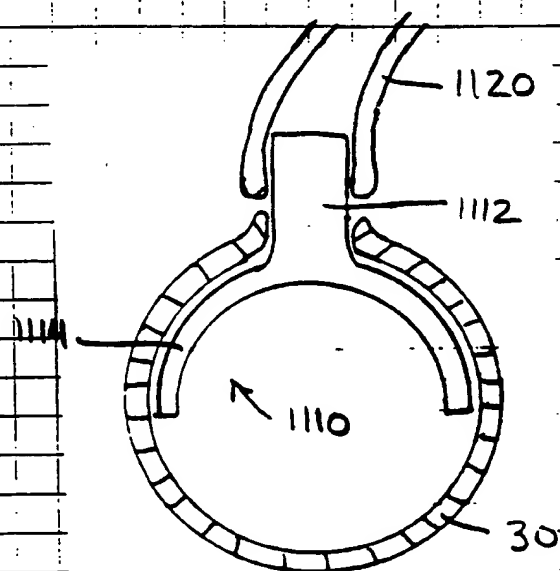
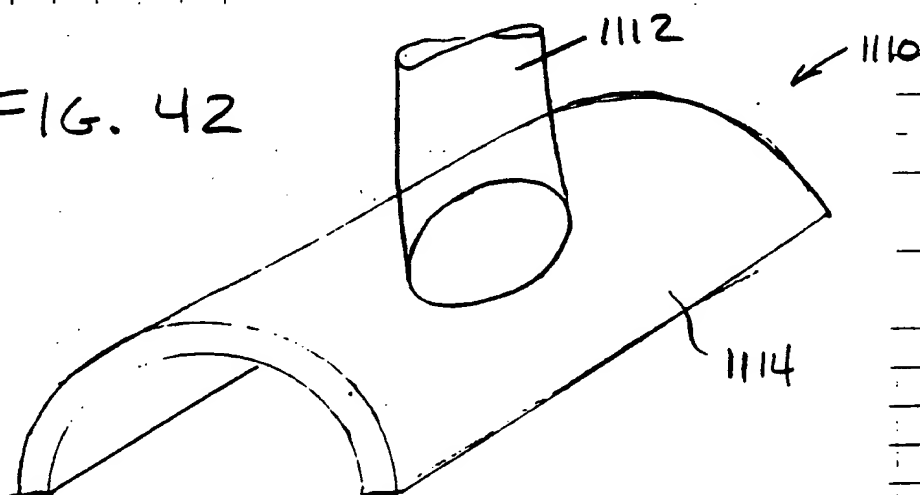


FIG. 43

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